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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,087	10/06/2003	Norbert Lamping	03100185AA	9922

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WHITHAM, CURTIS & CHRISTOFFERSON & COOK, P.C.
11491 SUNSET HILLS ROAD
SUITE 340
RESTON, VA 20190

EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,087	LAMPING ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 23-24 and 27-29 are drawn to methods of detecting disease comprising obtaining a biological sample from a patient, determining the concentration of at least one VGF protein or VGFARP peptide in said sample and comparing the concentration, wherein a difference between the concentration of the VGF protein or VGF ARP peptide in the control sample is indicative of disease, classified, for example in class 435, subclass 7.1.

II. Claims 21-22 and 25-26 are drawn to methods of detecting disease comprising obtaining a biological sample from a patient, determining the concentration of at least one nucleic acids that encode VGF protein or VGFARP peptide in said sample and comparing the concentration, wherein a difference between the concentration of the nucleic acids that encode VGF protein or VGFARP peptide in the control sample is indicative of disease, classified, for example, in class 435, subclass 91.2.

III. Claims 30-43 are drawn to methods of prophylaxis or treatment of a neurological disease comprising administering a substance that causes modulation of the concentration of at least one VGF protein or VGFARP

peptide in a quantity sufficient to prevent or treat the neurological disease, classification dependent upon the identity of the recited "substance".

IV. Claims 44-50 and 53 (in part) are drawn to VGFARP peptides and a pharmaceutical composition comprising the VGF protein or VFGFARP peptide, classified for example in class 530, subclass 300.

V. Claims 51-52, 53 (in part) and 57, drawn to nucleic acids that encode VGFARP peptides and a pharmaceutical composition comprising the a nucleic acid that encodes the VGF protein or VGFARP peptide, classified for example, in class 536, subclass 23.1.

VI. Claims 54-56 are drawn to antibodies to VGF protein or VGFARP peptide, classified, for example, in class 530, subclass 387.1.

Inventions I and II are directed to related but distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Group I is drawn to measuring protein and Group II is drawn to measuring DNA, thus the inventions have a different method steps and do not overlap in scope. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants, i.e., prior art anticipating a method of detecting the protein would not render the method of detecting

the DNA obvious. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I-II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the methods of diagnosis of Groups I and II do not share any common method steps with the method of treatment of Group III, and art anticipating the method of diagnosis would not anticipate or render obvious the method of treatment. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I-II and IV-V are directed to unrelated products and processes. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, Groups I-II are methods of diagnosis comprising measurement of VGF protein or VGFARP peptide (Group I) or the nucleic acids encoding the VGF protein or VGFARP peptide (Group II) and comparing the concentration of said proteins or nucleic acids in

the samples, wherein a difference between the concentration of said proteins or nucleic acids in the control sample is indicative of disease. The proteins and nucleic acids obtained in the samples as recited in Groups I and II are not the same as the isolated proteins and nucleic acids of Groups IV-V. Measurement of protein is generally conducted by immunoassay using antibodies and measurement of nucleic acid is generally conducted by PCR, Northern or Southern blotting using nucleic acid primers. There is no indication in the recitation of method steps that the methods of diagnosis in Groups I-II involve use of the isolated proteins and nucleic acids of Groups III-IV. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibodies of the claimed invention could be used in therapeutic applications or in assays studying the function of VGF or VGFARP peptide (i.e. to block function of endogenous peptide). Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction

is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the antibodies of Group VI are not used in methods of diagnosis comprising measurement of the nucleic acids encoding the VGF protein or VGFARP peptide and comparing the concentration of said nucleic acids in the samples, wherein a difference between the concentration of said nucleic acids in the control sample is indicative of disease (Group II). A search revealing the antibodies to VGF protein or VGFARP peptide would not anticipate or render obvious methods comprising the measurement of VGF or VGFARP DNA, thus because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions III and IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the peptides of Group IV, the nucleic acids of Group V and the antibodies of Group VI, ***might be*** used in the methods of prophylaxis or treatment of a neurological disease of

Group III, however, as indicated by the claims (for instance 34 and 35), the scope of the substances that can be administered for treatment method of Group III is far broader than the individual products of Groups of IV, V or VI. A method of administering proteins is not anticipated or rendered obvious by the nucleic acid or the antibody, and a similar reasoning applies to the other Groups. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the inventions are distinct because they are patentably distinct products—prior art anticipating the protein would not anticipate or render obvious the DNA or vice versa. The polypeptide of Group IV and polynucleotide of Group V are patentably distinct inventions because polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of Groups IV and V together would

impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups IV and V have a separate status in the art as shown by their different classifications. There is alsoa search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups IV and V together.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the polypeptide of Group IV and the antibody of Group V are patentably distinct for the following reasons: while the inventions of both Groups IV and VI are polypeptides, in this instance the polypeptide of Group IV is a single chain molecule that functions as an growth factor, whereas the polypeptide of Group VI encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions that function to bind an epitope. Furthermore, searching the inventions of Groups IV and VI would impose a serious search burden. The inventions have a separate status in the art as shown by their different

classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. Whereas an amino acid sequence search of the full-length protein is necessary for a determination of novelty and non-obviousness of the protein, such a search is not required to identify the antibodies of Group VI. Furthermore, antibodies which bind to an epitope of a polypeptide of Group VI may be known even if the polypeptide of Group IV is novel. In addition, the technical literature search for the polypeptide of Group IV and the antibody of Group VI are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Finally, prior art anticipating the antibody would not render the protein obvious. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant the polynucleotide of Group V and the antibody of Group VI are patentably distinct for the following reasons. The antibody of Group VI includes IgG molecules that comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions. Polypeptides, like the antibodies of Group VI, which are composed of amino

acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group V will not encode an antibody of Group VI, and the antibody of Group VI cannot be encoded by a polynucleotide of Group V. Therefore the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups V and VI would impose a serious search burden since a search of the polynucleotide of Group V would not be used to determine the patentability of an antibody of Group VI, and vice-versa. The search of the polypeptides and the polynucleotides are not coextensive. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: **VGFARP PEPTIDE**. The species are independent or distinct because they are separate molecules; one species of VGFARP peptide would not anticipate or render obvious a different species.

Applicant must elect a single species of amino acid sequence as recited in claims 2-3; 48-49 (elect by sequence identifier, i.e., SEQ ID NO: XX).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 4-47 and 50-57 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species: **SUBSTANCES.** The species are independent or distinct because a substance such as an antibody would not render obvious or anticipate a protein, nucleic acid, antisense nucleic acid, a ribozyme, etc. Similar reasoning applies to all the different substances on the list.

a. Antibodies directed against VGF proteins

b. VGFARP peptides or VGF proteins

c. NGF

d. BNDF

e. NT-3

f. NT-3

g. Substances that inhibit processing of VGF proteins

h. Antagonists of VGFARP peptides or VGF proteins

i. Nucleic acids which code for VGF proteins or VGFARP peptides

j. Nucleic acids which code for NGF

k. Nucleic acids which code for BNDF

l. Nucleic acids which code for NT-3

m. Substances which promote the processing of VGF proteins

n. Agonists of VGFARP peptides or VGF proteins.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-33 and 36-57 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER